Remarks

Claims 20-35 are pending in the subject application. By this Amendment, Applicants have added new claims 36-38. Support for the new claims can be found throughout the subject specification. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 20-38 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

As an initial matter, the Examiner has requested that the "Cross-Reference to Related Application" section in the subject application be amended to update the status of parent application 09/648,864. By this Amendment, Applicants have amended the "Cross-Reference to Related Application" section of the subject specification to indicate that the parent '864 application is now abandoned.

Claims 20-35 are rejected under 35 USC §112, first paragraph, as nonenabled by the subject specification. The Examiner acknowledges that the claimed methods are enabled for using interferons and interferon chimeras, but asserts that the specification does not enable methods using "biologically active fragments of these molecules." Applicants respectfully traverse this ground of rejection.

Applicants respectfully assert that the claims are enabled by the subject specification. As the Examiner is aware, under the enablement requirement of 35 USC §112, a patent application must teach an ordinarily skilled artisan "how to make" and "how to use" the claimed invention. Applicants respectfully assert that an ordinarily skilled artisan, having the benefit of the teachings of the subject application, can readily produce fragments of the various interferon proteins and test those fragments for biological activity (*e.g.*, the ability to downregulate IgE production). The level of skill of a person in the biotechnology arts is high and methods for preparing fragments of a protein are well known in the art. In addition, methods for testing the fragments to determine if they have the requisite biological activity are disclosed in the subject specification (see, for example, Example 1 and Example 6 therein). Applicants respectfully submit that while some experimentation may be necessary, it is not controlling on the issue of enablement where the experimentation is routine. *Ex parte Jackson*, 217 USPQ 804, 807 (Bd. Pat. App. & Int. 1982) ("The test [for undue experimentation] is not merely quantitative, since a considerable amount of experimentation is

permissible, if it is merely routine . . .") (emphasis added); *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)("Enablement is not precluded by the necessity for some routine screening.")(emphasis added). Preparation of protein fragments and the testing thereof for biological activity is routine in the art. Thus, Applicants respectfully assert that the subject specification teaches the ordinarily skilled artisan "how to make" and "how to use" the claimed invention. The Examiner asserts that "it is not routine in the art to screen large numbers of fragments potentially meeting the limitations of the claims when the expectation of obtaining similar activity is unpredictable." In the *Wands* case, the issue was the screening of hybridomas to find those that produced an antibody that bound to a particular antigen with high affinity. The court in *Wands* agreed that the preparation and screening of hundreds or thousands of hybridomas was routine and did not constitute undue experimentation. In the instant case, Applicants have explained that the making and screening of protein fragments is routine. Accordingly, Applicants respectfully assert that the pending claims are enabled by the subject specification. In view of the above remarks, reconsideration and withdrawal of the rejection under 35 USC §112, first paragraph, is respectfully requested.

Claims 20-35 are rejected under 35 USC §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner asserts that the subject specification does not provide written description of fragments of interferons that could be used in the claimed methods. Under this rejection, the Examiner asserts that "there is no description of the required structural and functional features of the such fragments. . . ." Applicants traverse this ground of rejection.

Applicants respectfully assert that there is adequate written description in the subject specification to convey to the ordinarily skilled artisan that they had possession of the claimed invention. Interferon tau proteins are well characterized in the art in regard to their structural and functional features. The primary amino acid sequence of interferon tau is well known in the art. As Applicants have stated in regard to the enablement rejection, methods for preparing fragments from a full length protein are also well known in the art. Thus, it follows that the structure of any fragment of interferon tau is known in the art and every fragment can be tested for function, *i.e.*, biological activity as recited in the claim, without resort to undue experimentation, using techniques that are

routine in the art. It is well settled in patent law that an application need not teach, and preferably omits, that which is well known or conventional in the art. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81 (Fed. Cir. 1986). Thus, there can be sufficient written description of an invention even if all the species of the genus are not explicitly disclosed in the specification. Accordingly, Applicants respectfully assert that the subject specification does provide written description for fragments of an interferon molecule as recited in the claimed methods. Reconsideration and withdrawal of the rejection under 35 USC §112, first paragraph, is respectfully requested.

Claim 20-35 are rejected under 35 USC §112, second parargraph, as indefinite. The Examiner asserts that claims 20, 28, and 35 are indefinite in the recitation of "to a person or animal in need of suppression or inhibition of allergen-specific IgE production" and that claims 21-27 and 29-34 are rejected insofar as they are dependent on rejected claims 20 and 28. The Examiner states that claims 20, 28, and 35 are rejected because there is no definition in the specification of an "IgE-related condition." Thus, Applicants are unsure as to whether the Examiner is indicating that the language "allergen-specific IgE production" or "IgE-related condition" is indefinite. If the latter, then Applicants note that the rejected independent claims 20, 28, and 35 do not recite "IgE-related condition" therein. If the former, Applicants respectfully assert that claims 20 and 35 are definite in their recitation of "allergen-specific IgE production." An ordinarily skilled artisan would understand that the language refers to IgE production induced and directed to a specific allergen. As to rejected claim 28, Applicants note that the claim recites "proliferation of IgE-producing cells." Applicants also assert that this language is definite and clear. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §112, second paragraph, is respectfully requested.

Claims 20 and 22-35 are rejected under 35 USC §§102(a) and (e) as anticipated by U.S. Patent No. 5,906,816 (Soos *et al.*). In addition, claims 20, 21, 27, 28, 34, and 35 are rejected under 35 USC §102(b) as anticipated by Mujtaba *et al.* (1998). The Examiner asserts that the '816 patent teaches mammalian interferon tau and that it is useful for the treatment of autoimmune disease. In regard to the Mujtaba *et al.* reference, the Examiner asserts that the reference teaches the inhibition of myelin basic protein (MBP) induced proliferation of B cells from EAE mice using interferon tau and that such treatment would inherently result in the suppression of IgE production. Applicants respectfully traverse these grounds of rejection.

Applicants respectfully assert that the '816 patent and the Mujtaba *et al.* reference do not anticipate the claimed invention. In making these rejections, the Examiner asserts that the use of interferon tau to treat autoimmune disorders or allergy would "inherently result in suppression of IgE production" and concludes that claims 20, 27, 28, 34, and 35 are anticipated. Under the rejection based on the '816 patent, the Examiner further asserts that any "person suffering from an autoimmune disease who also suffered from allergy would be in need of such suppression and the limitations of claims 20, 23, 24, 30 and 36 [sic] are thus also anticipated" (emphasis added). Applicants respectfully assert, however, that the '816 patent does not teach or suggest treatment of a person that has an autoimmune disorder and who is need of inhibition of allergen-specific IgE production or inhibition of proliferation of IgE producing cells. Nor has the Examiner pointed to evidence in the art of a person having both an autoimmune disorder and who is also in need of inhibition of allergen-specific IgE production or inhibition of proliferation of IgE producing cells. That a person **may** suffer from both an autoimmune disorder and a disorder that involves allergen-specific IgE production or proliferation of IgE producing cells, does not lessen or remove the legal requirement that in order to anticipate under 35 USC §102, a single reference **must** teach each and every element of the claimed invention. In order to anticipate, a single reference must disclose within the four corners of the document each and every element and limitation contained in the rejected claim. *Scripps Clinic & Research Foundation v. Genentech Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991). As an example, Applicants note that there **may** be people that suffer from autoimmune disorders and cancer, or autoimmune disorders and narcolepsy, or autoimmune disorders and any other non-autoimmune disease known in the art. However, it is clear under the patent laws of the United States that the earlier disclosure of a composition that was only known in the art as useful in treating an autoimmune disorder would **not** anticipate a later discovery that the same composition was useful in treating cancer, or narcolepsy, or any other non-autoimmune disease known in the art even though there may have been a person being treated for an autoimmune disorder that also had cancer, *etc.* To anticipate, the prior art must have recognized that the composition also had efficacy in treating the cancer, *etc.* The same applies in the instant case where the disorder or condition involves allergen-specific IgE production or proliferation of IgE producing cells.

Applicants also respectfully assert that the Mujtaba *et al.* reference fails to anticipate the claimed invention. As noted above, claims 20, 21, 27, 28, 34, and 35 are included under the rejection. Independent claim 20 recites administering interferon tau to a person or animal in need of suppression or inhibition of allergen-specific IgE production. Independent claim 28 recites administering interferon tau to a person or animal in need of suppressing or inhibiting proliferation of IgE-producing cells. Claim 35 recites identifying a person or animal in need of suppression or inhibition of allergen-specific IgE production. The Mujtaba *et al.* reference does not teach or suggest administering interferon tau to a person or animal **in need of** suppression or inhibition of allergen-specific IgE production or proliferation of IgE-producing cells, nor does the cited reference teach or suggest the first step set forth in the claimed method, *i.e.*, **identifying a person or animal** in need of suppression or inhibition of allergen-specific IgE production. The Mujtaba *et al.* reference is directed to work using mice that have experimental allergic encephalitis (EAE). There is **no relation** between EAE and allergen-specific IgE production or proliferation of IgE-producing cells. EAE is a model for an autoimmune disorder, not for an allergic disorder. There is no teaching or suggestion in the Mujtaba *et. al.* reference that the mice also had a disorder involving allergen-specific IgE production or proliferation of IgE-producing cells. A person of ordinary skill in the art would not look to publications pertaining to the EAE model in order to identify an animal in need of suppression or inhibition of allergen-specific IgE production or for teachings pertaining to suppression or inhibition of allergen-specific IgE production. Thus, the cited reference does not teach or suggest identifying a person or animal in need of suppression or inhibition of allergen-specific IgE production, nor does it teach or suggest administering an effective amount of interferon tau to the identified person or animal.

In regard to the rejections of claim 28, and claims dependent therefrom, Applicants note that the claims recite that interferon tau is administered "to a person or animal in need of suppressing or inhibiting proliferation of IgE-producing cells." There is no teaching or suggestion in either of the cited references of administering interferon tau to suppress or inhibit proliferation of IgE-producing cells. If the Examiner disagrees with Applicants' remarks concerning the cited references, then Applicants respectfully request that the Examiner indicate the specific teaching in the references in a further communication to Applicant's undersigned representative.

It is well established that a new use for a known composition of matter is patentable subject matter. It is also well established in patent law that the presence of an inherent property or effect must be grounded on more than speculation, it must be a certainty and a person of ordinary skill in the art must necessarily recognize its presence. *Scaltech Inc. v. Retec/Tetra L.L.C.*, 48 USPQ2d 1037 (Fed. Cir. 1998), revised and reissued, 51 USPQ2d 1055, 1059 (Fed. Cir. 1999) ("Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient to establish inherency.") (emphasis added); *Crown Operations International Ltd. v. Solutia Inc.*, 62 USPQ2d 1917 (Fed. Cir. 2002). Applicants respectfully assert that at the time of the present invention it was not a certainty that the administration of interferon tau would result in suppression of IgE production or inhibition of proliferation of IgE-producing cells. It is generally acknowledged in the art that B lymphocyte production of antibodies (immunoglobulins) is a complex process. There are five immunoglobulin heavy chains that determine the properties of an antibody molecule. These heavy chains determine what is known as the immunoglobulin (and antibody) isotype, of which IgE is but one type. Mature B cells constitutively express immunoglobulins of the IgM and IgD isotype on their surfaces. Antigen stimulation and T helper cell involvement directly, and via cytokines, result in clonal expansion of antigen-specific B cells. There is also the complex event of immunoglobulin gene rearrangement known as isotype switching. Normally, the IgE isotype that is associated with allergies is not expressed at significant levels and, therefore, IgE serum levels tend to be low. The biochemical and molecular events and mechanisms associated with IgE-specific allergy are so complex that it was impossible at the time of the present invention to predict that IgE-type allergies would be suppressed by interferon tau. This had to be determined empirically. Thus, Applicants respectfully assert that the inhibition or suppression of IgE production or proliferation of IgE-producing cells by interferon tau was not "inherent" in the disclosure of treatment of patients with interferon tau in the '816 patent and the Mujtaba *et al.* reference cited by the Examiner.

In view of the above remarks, reconsideration and withdrawal of the rejections under 35 USC §102 is respectfully requested.

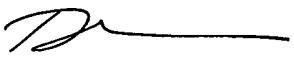
It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



Doran R. Pace
Patent Attorney
Registration No. 38,261
Phone No.: 352-375-8100
Fax No.: 352-372-5800
Address: P.O. Box 142950
Gainesville, FL 32614-2950

DRP/kmm